



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES

APR 20 2007

DECISION MEMORANDUM

SUBJECT: Unconditional Registration of the Manufacturing Use Product Canadian Wilderness Oil (EPA Reg. No. 82016-2) and Fresh Cab® (EPA Reg. No. 82016-1)

FROM: Janet L. Andersen, Ph.D., Director
Biopesticides and Pollution Prevention Division

TO: Debra Edwards, Ph.D., Director
Office of Pesticide Programs

RECOMMENDATION:

BPPD recommends the unconditional registration, under FIFRA § 3(c)(5), of the manufacturing use product Canadian Wilderness Oil and the end use product Fresh Cab®, which contain the active ingredient balsam fir oil.

SUMMARY OF RATIONALE:

Active Ingredient and Proposed Use

Balsam fir oil is a technical grade active ingredient (TGAI) that represents 10.0% by weight of the manufacturing use product (MP) Canadian Wilderness Oil, and 2.0% by weight of the end use product (EP) Fresh Cab®. Canadian Wilderness Oil is to be used to formulate Fresh Cab®, which is a non-food use biochemical pesticide to be used to repel rodents in non-living spaces indoors and in enclosed spaces outdoors. Fresh Cab® repels rodents by emitting an odor that is offensive to rodents but pleasant to humans.

Human Exposure and Risks

Evaluations of mammalian toxicology data and waivers are sufficient to support the unconditional registration of this biochemical pesticide for the proposed uses for Canadian Wilderness Oil and Fresh Cab[®]. Acceptable acute toxicity guideline studies were submitted for the balsam fir oil TGAI and the Canadian Wilderness Oil MP. Based on the results of those studies, the required acute toxicity studies for the Fresh Cab[®] EP were waived by the Agency. Waivers were also granted for immunotoxicity, 90-day dermal toxicity, and inhalation toxicity for Canadian Wilderness Oil and Fresh Cab[®]. No additional toxicological data are needed.

There are also no significant risk issues identified for dietary risk, residential risk, or ground and surface water contamination resulting from use of the products. Occupational risk is mitigated as long as the Canadian Wilderness Oil MP is used according to label directions. Based on the review of the submitted human health data and waiver rationales, it is expected that there are no unreasonable adverse effects to human health.

Ecological and Environmental Exposure and Risks

The submitted ecological data and waiver rationales support a conclusion that there will be no unreasonable adverse effects to nontarget organisms or to the environment expected as a result of the intended use of Canadian Wilderness Oil or Fresh Cab[®]. Data waivers were granted for ecological effects data requirements by the Agency based on the low toxicity of the balsam fir oil and Canadian Wilderness Oil and the minimal risk of exposure expected from the use pattern of Fresh Cab[®]. When the products are used according to label directions, there is no expectation of risk to non-target birds, aquatic organisms, or plants.

Efficacy

Efficacy data submitted for the EP (MRID 46784416) indicated the product provides approximately 68% repellency to mice over a 31-day period. While the study design contained certain flaws, the submitted study was determined to be acceptable. No additional efficacy data are needed.

Data Gaps and Requirements/Labeling

The Agency evaluated all of the data submitted in connection with the initial registration of Canadian Wilderness Oil MP and Fresh Cab[®] EP and determined that these data are sufficient to satisfy current registration guideline requirements. Therefore, Canadian Wilderness Oil and Fresh Cab[®] are eligible for unconditional registration.

Additional information on this registration decision may be found in the Balsam Fir Oil Biopesticide Registration Action Document (BRAD).

OFFICE DIRECTOR CONCURRENCE:

The Biopesticides and Pollution Prevention Division (BPPD) recommends that the manufacturing use product Canadian Wilderness Oil and the end-use product Fresh Cab[®], which contain the new active ingredient balsam fir oil, be unconditionally registered under 3(c)(5) of FIFRA as a rodent repellent.

Concurrence: Walter Edmunds

Non Concurrence: _____

Date: April 24, 2007